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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,325	08/19/2003	Hans Weiher	VOS-44 CON	6657
1473	7590	10/08/2004	EXAMINER	
FISH & NEAVE LLP 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			HARLE, JENNIFER I	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,325

Applicant(s)

WEIHER ET AL.

Examiner

Jennifer I. Harle

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1654

DETAILED ACTION

Claims 1-10 are pending. Claims 1-10 are subject to an Election/Restriction Requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-10 are drawn to a plethora of inhibitors, namely, γ -GT inhibitors, classified in various classes and subclasses.

Applicants are required to elect a specific inhibitor.

As the invention is drawn to thousands of different inhibitors, which vary distinctly in their structures and functions as the pharmaceutical itself or an intermediate in the preparation of a compound, i.e. an isoxazoleacetic acid (nitrogen and oxygen ring containing compound) and its derivatives (resulting in an unlimited number of compounds as derivatives allow for substitutions, deletions and additions in any place in the compound and thus would potentially result in a lack of a known core), a butanoic acid (alkyl chain containing compound with boron) and its derivatives (resulting in an unlimited number of compounds as derivatives allow for substitutions, deletions and additions in any place in the compound and thus would potentially result in a lack of a known core), amino acids and peptides containing three component in the general formula only one of which is constant and the others are totally unknown and can be oligopeptides and polypeptides of unknown length and amino acids (i.e. natural and unnatural with multiple side chains, cyclics, etc.) (resulting in a total lack of a known core of the compound), peptidomimetic glutathione analogues that is a compound containing non-peptidic structural elements that are capable of mimicking or antagonizing the biological action(s) of

Art Unit: 1654

natural parent peptides and no longer have classical peptide characteristics such as enzymatically scissile peptidic bonds, moreover, it is generally accepted that they comprise fragments and may be modified or substituted (thus they would read on a plethora of compounds which would not be required to have a common core with each other let alone any of the other groups and are not disclosed as being required to do so)¹ and anilides which are any compound containing the univalent group C_6H_5NH- , derived from aniline, as acetanilide, C_8H_9NO and thus can encompass any thing that is attached to this group that would be utilized to prepare a pharmaceutical preparation.

These compounds/peptides/peptidomimetics are not required to have any specific core structure and can vary greatly within each of the groups themselves. Thus, an individual search is required of each individual compound. **Applicant is required to elect a specific inhibitor**, to which, the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the elected composition. This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentable distinct invention, in the absence of evidence to the contrary.

Should Applicants' traverse on the ground that the compounds are not patentable distinct, Applicants should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the invention unpatentable over the prior art, the evidence or admission may be used in a rejection under 103(a) of the other.

¹ Glossary of Medical Terms Used in Chemistry (IUPAC Recommendations 1998), I to X, 1998, <http://www.chem.qmul.ac.uk/iupac/medchem/ix.html>, printed October 4, 2004, pp. 1-7; and Barton, et al. US

Art Unit: 1654

All inhibitors falling outside the selected inhibitors will be withdrawn from consideration under 35 U.S.C. 121 and 37 CFR 1.142(b). Applicants may reserve the right to file divisional applications on remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventors must be amended in compliance with 37 CFR 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Finally, because of the plethora of inhibitors, classes and subclasses to be searched, the potential necessity of various structure searches and varying literature and/or sequence searches, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm.,.

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Ione Harle

October 4, 2004



MICHAEL MELLER
PRIMARY EXAMINER